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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/902,786 | 07/12/2001 | Edward F. Patz JR. | DUKE-227 | 6628 |
| 34610 | 7590 | 03/08/2004 | EXAMINER | |
| FLESHNER & KIM, LLP P.O. BOX 221200 CHANTILLY, VA 20153 | | | DAVIS, DEBORAH A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

5

Office Action Summary

Application No.

09/902,786

Applicant(s)

PATZ ET AL.

Examiner

Deborah A Davis

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the office action mailed February 26, 2004 is acknowledged. Claims 1, 5, 6, 11 and 18 are pending with claim 18 being withdrawn from consideration.

Election/Restrictions

2. Newly submitted claim 18 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Although claims 18 now depends from independent claim 1, it is drawn to a product that wherein its identification is not limited to the protein profiling system of claim 1.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 18 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 5, 6, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted

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elements are: a database that stores protein profiles. Claim 1, is drawn to a protein profiling system that has a protein fractionation unit, a mass spectrometer and a protein processing unit. When data is received and analyzed, storage of data is needed. One skilled in the art would recognize that a database is required with a data processing unit, otherwise, how is the analyzed data stored. In addition, the instant specification supports the need for this critical element on page 11, paragraph 65 and Figure 1. Applicant is invited to show support for the omission of this critical element.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 5-6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yates et al (USP#5,538,897).

Yates et al teaches the use of mass spectrometry fragmentation patterns of peptides to identify amino acid sequences in databases. A peptide is analyzed by tandem mass spectrometer to yield a peptide fragment mass spectrum. A protein sequence database or a nucleotide sequence database is used to predict one or more fragment spectra for comparison with the fragment spectrum, as recited in claims 1 and 4 (see abstract). A fractionation unit such as gel filtration

chromatography and/or high performance liquid chromatography (HPLC) is used to separate the proteins before being introduced to mass spectrometer (col. 2, lines 51-55). The proteins are separated into fragments to be analyzed by mass spectrometer (col. 2, lines 65-67). The present invention can be used in connection with diagnostic applications such as some forms of cancer, genetic disease and cystic fibrosis (col. 17, lines 62-67 and col. 18, lines 25-38).

According to the definition of Neural Network in the specification, Yates et al describes such a system that provides a protein sequence database that is used to predict one or more fragment spectra for comparison with derived fragment spectrum. The various predicted mass spectra are compared to the experimentally derived fragment spectrum using a "closeness-of-fit measure" preferable calculated with a two-step process, including a calculation of a preliminary score and, for the highest scoring predicted spectra, calculation of a correlation function as recited in claim 5 (col. 5, lines 1-30, col. 6, lines 38-55 and Figures 6A-6E). The protein data base system assigns peak intensities values to each fragment, which values include the predicted mass spectra and the experimentally-derived fragment spectrum as recited in claim 6 (col. 5, lines 53-67). With respect to the new limitations cited in claim 1 of a protein fractionation unit that separates a protein content of at least two tissue samples, one of a normal cell and the other a tumor cell and comparing the two is considered intended use and will not be given patentable weight.

Response to Arguments

7. Applicant argues that the reference of Yates et al fail to disclose or suggest the recited protein profiling system for identification of a protein biomarker and neither does the instant reference disclose or suggest that its database may be omitted.
9. This argument is not found persuasive because Yates et al disclose a protein profiling system ***consisting essentially*** of a protein fractionation unit, a mass spectrometer, a protein data processing unit, and a database. With respect to the omission of a database, the Examiner deemed this element to be essential. When data of protein profiles are received, analyzed and identified by the protein-processing unit, storage of the data is needed for comparison to other protein profiles. One skilled in the art would recognize that a database is required with a data processing unit, otherwise, how is the analyzed data stored for use. In addition, the instant specification supports the need for this critical element on page 11, paragraph 65 and Figure 1. Applicant is invited to show support for the omission of this critical element.

Applicant has amended the claims to change tumor cell to specimen cell and normal cells to reference cells. The reference of Yates et al discloses proteins that are separated into fragments to be analyzed by mass spectrometer (col. 2, lines 65-67) and can be used in connection with diagnostic applications such as some forms of cancer, genetic disease and cystic fibrosis (col. 17, lines 62-67 and col. 18, lines 25-38). Examiner believes that this disclosure

encompasses the amended changes; therefore for reasons aforementioned, the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

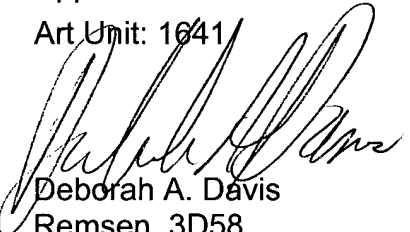
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Deborah A. Davis

Remsen, 3D58

March 3, 2004***



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03/03/04